ATTACHMENT A

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Docket No.: 22841.018

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Customer No.: 29277
NICOLSON et al.	:	Confirmation No.: 6172
Serial No.: 09/640,526	:	Group Art Unit: 1714
Filed: August 17, 2000	:	Examiner: Edward Cain
For: EXTENDED WEAR OPHTHALMIC LENS	:	

AMENDMENT AND RESPONSE UNDER 37 CFR §1.111 TO OFFICE ACTION OF NOVEMBER 6, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed on November 6, 2004, Applicants submit the following amendments and remarks, and a petition of a three month extension of the time to respond. The Examiner is requested to enter the following amendments and consider the accompanying remarks. Reconsideration is respectfully requested.

Amendments to the claims are reflected in the listing to the claims that begins on page 3 of this paper.

Support for the New Claims begin on page 28

Remarks begin on page 29 of this paper.

Enclosed with this paper is a Supplemental Information Disclosure Statement.

Also enclosed with this paper is a petition under 37 CFR § 1.136 for a three month extension of the time to respond, together with a Fee Transmittal form in duplicate authorizing the Commissioner to charge the petition fee under 37 CFR § 1.17(a)(3) for the extension and any other fees that may be due to Deposit Account Number 500417, McDermott Will & Emery, Washington D.C.

Please amend the claims as set forth below and enter the following remarks.

AMENDMENT TO THE CLAIMS:

Claims 1-158 (Cancelled).

Claim 159 (Currently Amended) A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

a) preparing a lens formulation comprising an oxyperm polymerizable material selected from the group consisting of fluorine-containing macromers and flourine-containing monomers and an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones, wherein said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of said lens formulation;

b) placing said lens formulation in a lens mold;

c) polymerizing [[-]]said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyperm polymerizable material and said ionoperm polymerizable material of said lens formulation form separate oxyperm and ionoperm phases; said lens core material having an oxygen permeability equal to or greater than 77 barrers;

d) removing said lens core material from said lens mold;

e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more biocompatible with the ocular tissue and ocular fluids than said core material alone; and

f) hydrating the treated lens core material to produce a hydrated extended wear contact lens; [[.]]

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as extended wear lens that is worn for a continuous period of at least 24 hours with corneal swelling of less than about 8%.

Claim 160 (Previously Presented) The method of claim 159 wherein the surface modification treatment is selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes.

Claim 161 (Previously Presented) The method of claim 159 wherein the surface modification treatment is a plasma treating process.

Claim 162 (Previously Presented) The method of claim 161wherein said oxyperm polymerizable material is a fluorine-containing macromer and said ionoperm polymerizable material is N-vinyl pyrrolidone.

Claim 163 (Currently Amended) An extended wear contact lens comprising a core polymeric material having and upper and lower surfaces, said core polymeric material comprising a silicone copolymer which provides a high ion permeability and a high oxygen permeability; wherein said silicone copolymer comprises an oxyperm polymerizable material selected from the group consisting of fluorine-containing macromers and fluorine-containing monomers, and an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones; said core polymeric material having an oxygen permeability equal to or greater than 77 barrers; wherein said surfaces are hydrophilically modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and

irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling.

Claim 164 (Previously Presented) The extended contact lens of claim 163 wherein said core polymeric material comprises a fluorine containing macromer, and N-vinyl pyrrolidone.

Claim 165 (Previously Presented). The extended contact lens of claim 164 wherein said surfaces are modified by a plasma treating process.

Claim 166 (Previously Presented) The extended contact lens of claim 165 wherein said extended lens can be continuously worn for about 7 days with less than about 8% corneal swelling.

Claim 167 (Previously Presented) The extended contact lens of claim 163 wherein said extended lens is worn for about 30 days.

Claim 168 (Currently Amended) A hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having an oxygen permeability equal to or greater than 77 barrers, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion permeability, said core polymeric material having formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material selected from the group consisting of fluorine-containing macromers and fluorine-containing monomers, and

(b) an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones, wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids,

wherein said lens has an oxygen permeability of at least about 77 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater ~~grater~~ than about 6.4 x 10^{-6} [10-6] mm^2 [mm2]/sec or an Ionoton Ion Permeability Coefficient of greater than about 0.4 x 10^{-6} [10-6] cm^2 [cm2]/min, wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes, wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling.

Claim 169 (Previously Presented) The hydrogel contact lens of claim 168 wherein said core polymeric material comprises a fluorine containing macromer as said oxyperm material and N-vinyl pyrrolidone as said ionoperm material.

Claim 170 (Previously Presented) The hydrogel contact lens of claim 169 wherein said surfaces are modified by a plasma treating process.

Claim 171 (Previously Presented) The hydrogel contact lens of claim 170 wherein said lens can be worn for about 7 days with less than about 8% corneal swelling.

Claim 172 (Previously Presented) The hydrogel contact lens of claim 170 wherein said lens is worn for about 7 days with less than about 4% corneal swelling.

Claim 173 (Previously Presented) The hydrogel contact lens of claim 170 wherein said lens can be continuously worn for about 30 days.

Claim 174 (Previously Presented) The hydrogel contact lens of claim 169 wherein said lens has an oxygen permeability of at least about 81 barrers.

Claim 175 (Currently Amended) A method of using a contact lens as an extended wear lens, said lens having ophthalmically compatible modified surfaces, said lens being suited to

extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids, said lens comprising a polymeric material which has a high oxygen permeability and a high ion or water permeability, and which has an oxygen permeability equal to or greater than 77 barrers, said polymeric material being formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material selected from the group consisting of fluorine-containing macromers and fluorine-containing monomers, and

(b) an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones, wherein said modified surfaces are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes: wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids; wherein said lens allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids; and wherein said ophthalmic lens has an oxygen permeability of at least about 70 barters and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.4 x 10^{-6} [10-6] cm^2 [cm2] /sec or (2) an Ionoflux Diffusion Coefficient of greater than about 6.4 x 10^{-6} [10-6] mm2 /min, wherein said ion permeability is measured with respect to sodium ions; said method comprising the steps of:

(a) applying said lens to the ocular environment, and

(b) allowing said lens to remain in intimate contact with the ocular environment for a period of at least 24 hours.

Claim 176 (Previously Presented) The method of claim 175 wherein said lens has an oxygen permeability of at least about 81 barrers.

Claim 177 (Previously Presented) The method of claim 175 wherein said intimate contact period is at least 4 days.

Claim 178 (Previously Presented) The method of claim 175 wherein said intimate contact period is about 7 days.

Claim 179 (Previously Presented) The method of claim 175 wherein said intimate contact period is about 14 days.

Claim 180 (Previously Presented) The method of claim 175 wherein said intimate contact period is about 30 days.

Claim 181 (Previously Presented) The method of claim 175, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 8% corneal swelling.

Claim 182 (Previously Presented) The method of claim 175, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less than about 6% corneal swelling.

Claim 183 (Previously Presented) A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

a) preparing a lens formulation comprising an oxyperm polymerizable material, and an ionoperm polymerizable material, wherein said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of said lens formulation;

b) placing said lens formulation in a lens mold;

c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyperm polymerizable material and said ionoperm polymerizable material of said lens formulation form separate oxyperm and ionoperm phases; said lens core material having an oxygen permeability equal to or greater than 69 barrers;

d) removing said lens core material from said lens mold;

e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and

f) hydrating the treated lens core material to produce a hydrated extended wear contact lens,

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as extended wear lens that is worn for a continuous period of at least 24 hours without having substantial amounts of lipid adsorption.

Claim 184 (Previously Presented) The method of claim 183 wherein the surface modification treatment is selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes.

Claim 185 (Currently Amended) The method of claim 183 wherein the surface modification treatment includes [is] a plasma treating process.

Claim 186 (Currently Amended) The method of claim 185 wherein [said oxyperm polymerizable material is a fluorine macromer and] said ionoperm polymerizable material is N-vinyl pyrrolidone.

Claim 187 (Previously Presented) An extended wear contact lens comprising a core polymeric material and upper and lower surfaces, said core polymeric material formed from a silicone copolymer which provides a high ion permeability and a high oxygen permeability; said silicone copolymer comprising an oxyperm polymerizable material, and an ionoperm polymerizable material; said core polymeric material having an oxygen permeability equal to or greater than 69 barrers; wherein said surfaces are hydrophilically modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

Claim 188 (Currently Amended) The extended contact lens of claim 187 wherein said core polymeric material is formed from N-vinyl pyrrolidone.

Claim 189 (Previously Presented) The extended contact lens of claim 188 wherein said surfaces are modified by a plasma treating process.

Claim 190 (Previously Presented) The extended contact lens of claim 189 wherein said extended lens can be continuously worn for about 7 days with less than about 7 % corneal swelling.

Claim 191 (Currently Amended) The extended contact lens of claim 187 wherein said extended wended wear lens can be worn for about 30 days.

Claim 192 (Currently Amended) A siloxane hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having an oxygen permeability equal to or greater than 69 barrers, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion

permeability, said core polymeric material being formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material, and

(b) an ionoperm polymerizable material,

wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids, wherein said lens has an oxygen permeability of at least about 69 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater ~~grater~~ than about 6.4×10^{-6} ~~10-6~~ mm2/sec or an Ionoton Ion Permeability Coefficient of greater than about 0.4×10^{-6} ~~10-6~~ cm^2[cm2]/min,

wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes,

wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

Claim 193 (Previously Presented) The hydrogel contact lens of claim 192 wherein said core polymeric material is formed from N-vinyl pyrrolidone as said ionoperm material.

Claim 194 (Previously Presented) The hydrogel contact lens of claim 193 wherein said surfaces are modified by a plasma treating process.

Claim 195 (Previously Presented) The hydrogel contact lens of claim 194 wherein said lens can be worn for about 7 days in continuous contact with ocular tissues and fluids with less than about 8% corneal swelling.

Claim 196 (Previously Presented) The hydrogel contact lens of claim 194 wherein said lens is worn for about 7 days with less than about 4% corneal swelling.

Claim 197 (Previously Presented) The hydrogel contact lens of claim 194 wherein said lens can be continuously worn for about 30 days.

Claim 198 (Previously Presented) The hydrogel contact lens of claim 194 wherein said lens has an oxygen permeability of at least about 77 barrers.

Claim 199 (Currently Amended) A method of using a contact lens as an extended wear lens, said lens having ophthalmically compatible modified surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids, said lens comprising a polymeric material which has a high oxygen permeability and a high ion or water permeability, and which has an oxygen permeability equal to or greater than 69 barrers, said polymeric material being formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material, and

(b) an ionoperm polymerizable material,

wherein said modified surfaces are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes;

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids;

wherein said lens allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids without having substantial amounts of lipid absorption; and

wherein said ophthalmic lens has an oxygen permeability of at least about 70 barrers and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.4×10^{-6} [10-6] cm^2 [cm2]/sec or (2) an Ionoflux Diffusion Coefficient of greater than about 6.4×10^{-6} [10-6] mm^2 [mm2]/min, wherein said ion permeability is measured with respect to sodium ions;

said method comprising the steps of:

(a) applying said lens to the ocular environment, and

(b) allowing said lens to remain in continous intimate contact with the ocular environment for a period of at least 24 hours without having substantial amounts of lipid adsorption.

Claim 200 (Previously Presented) The method of claim 199 wherein said lens has an oxygen permeability of at least about 77 barrers.

Claim 201 (Previously Presented) The method of claim 199 wherein said intimate contact period is at least 4 days.

Claim 202 (Previously Presented) The method of claim 199 wherein said intimate contact period is about 7 days.

Claim 203 (Previously Presented) The method of claim 199 wherein said intimate contact period is about 14 days.

Claim 204 (Previously Presented) The method of claim 199 wherein said intimate contact period is about 30 days.

Claim 205 (Previously Presented) The method of claim 199, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 8% corneal swelling.

Claim 206 (Previously Presented) The method of claim 199, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less than about 6% corneal swelling.

Claim 207 (Currently Amended) A method of forming a biocompatible lens having high oxygen permeability and high water permeability, said method comprising the steps of:

(a) forming a pre-polymer core formulation comprising an oxyperm polymerizable material, and an ionoperm polymerizable material, said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of said reactive components formulation;

(b) polymerizing the core formulation in an atmosphere substantially free from oxygen to form a biocompatible lens having a core and surfaces;

(c) altering the surface of said core material to produce a surface which is more hydrophilic than said core material; and

(d) autoclaving said lens at predetermined temperatures;

whereby said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids, and

whereby said lens allows ion permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said lens having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of contact for at least 24 hours,

wherein said biocompatible ~~ophthalmic~~ lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} [10-6] cm^2 [cm2] /sec or (2) by an Ionoflux Ion Permeability Coefficient of greater than about 1.5×10^{-6} [10-6] mm^2 [mm2]/min, wherein said ion permeability is measured with respect to sodium ions.

Claim 208 (Previously Presented) A method of forming a contact lens having high oxygen permeability and high water permeability, said method comprising:

(a) forming a polymeric core material in the shape of a contact lens having an inner and outer surface; and

(b) altering the surfaces of said core material to produce new surfaces that are more hydrophilic than said core material,

wherein said lens having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of contact for at least 24 hours.

Claim 209 (Previously Presented) The method of claim 208 wherein said intimate contact period is about 7 days.

Claim 210 (Previously Presented) The method of claim 208 wherein said intimate contact period is about 30 days.

Claim 211 (Previously Presented) The method of claim 208 wherein said lens is autoclaved at predetermined temperatures.

Claim 212 (Previously Presented) A biocompatible contact lens having high oxygen permeability and high water permeability, said lens comprising:

(a) a polymeric core material in the shape of a contact lens having an inner and outer surface; and

(b) said surfaces of said core material being surface modified to produce new surfaces that are more hydrophilic than said core material,

wherein said lens having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of contact for at least 24 hours.

Claim 213 (Previously Presented) The lens of claim 212 wherein said intimate contact period is at least 4 days.

Claim 214 (Previously Presented) The lens of claim 213 wherein said intimate contact period is about 7 days.

Claim 215 (Previously Presented) The lens of claim 213 wherein said intimate contact period is about 14 days.

Claim 216 (Previously Presented) The lens of claim 213 wherein said intimate contact period is about 30 days.

Claim 217 (Previously Presented) The lens of claim 212, said lens being sterilized. temperatures.

Claim 218 (Currently Amended) A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

a) preparing a lens formulation comprising an oxyperm polymerizable material, and an ionoperm polymerizable material, wherein said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of reactive components of said lens formulation;

b) placing said lens formulation in a lens mold;

c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyperm polymerizable material and said ionoperm polymerizable material of said lens formulation form separate oxyperm and ionoperm phases; said lens core material having an oxygen permeability equal to or greater than 69 barrers;

d) removing said lens core material from said lens mold;

e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and

f) hydrating the treated lens core material to produce a hydrated extended wear contact lens,

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as an extended wear lens [that is worn] for a continuous period of at least 24 hours without having substantial amounts of lipid adsorption.

Claim 219 (Currently Amended) A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

a) preparing a lens formulation comprising an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, fluorine-containing macromers, siloxane-containing mononers and fluorine-containing monomers, and an ionoperm polymerizable material, wherein said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of reactive components of said lens formulation;

b) placing said lens formulation in a lens mold;

c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyperm polymerizable material and said ionoperm polymerizable material of said lens formulation form separate oxyperm and ionoperm phases; said lens core material having at least one continous pathway from said inner surface to said outer surface for oxygen transmission therethrough;

d) removing said lens core material from said lens mold;

e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and

f) hydrating the treated lens core material to produce a hydrated extended wear contact lens,

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as an extended wear lens [that is worn] for a continuous period of at least 24 hours with corneal swelling of less than about 8%.

Claim 220 (Previously Presented) The method of claim 219 wherein the surface modification treatment is selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes.

Claim 221 (Previously Presented) The method of claim 219 wherein the surface modification treatment is a plasma treating process.

Claim 222 (Previously Presented) The method of claim 221 wherein said oxyperm polymerizable material is a siloxane containing macromer or siloxane containing monomer and said ionoperm polymerizable material is N-vinyl pyrrolidone.

Claim 223 (Previously Presented) An extended wear contact lens comprising a core polymeric material and upper and lower surfaces, said core polymeric material comprising a silicone copolymer which provides a high ion permeability and a high oxygen permeability; wherein said silicone copolymer comprises an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, siloxane-containing monomers, fluorine-containing macromers, siloxane containing monomers and fluorine-containing monomers, and an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones, wherein said core polymeric material has at least

one continuous pathway from said upper surface to said lower surface for oxygen transmission; wherein said surfaces are hydrophilically modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling.

Claim 224 (Previously Presented) The extended contact lens of claim 223 wherein said core polymeric material is formed from a mixture comprising a siloxane-containing macromer or a siloxane monomer, and N-vinyl pyrrolidone.

Claim 225 (Previously Presented) The extended contact lens of claim 224 wherein said surfaces are modified by a plasma treating process.

Claim 226 (Previously Presented) The extended contact lens of claim 225 wherein said extended lens can be continuously worn for about 7 days with less than about 8 % corneal swelling.

Claim 227 (Previously Presented) The extended contact lens of claim 224 wherein said extended wear lens can be worn for about 30 days.

Claim 228 (Currently Amended) A hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having at least one continuous pathway between said surfaces for oxygen transmission therethrough, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion permeability, said core polymeric material formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, siloxane-containing monomers, fluorine-containing macromers and fluorine-containing monomers, and

(b) an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones,

wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids, wherein said lens has an oxygen permeability of at least about 70 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater than about 6.4×10^{-6} [10-6] mm^2 [mm2]/sec or an Ionoton Ion Permeability Coefficient of greater than about 0.4×10^{-6} [10-6] cm^2 [cm2] /min,

wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes,

wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling.

Claim 229 (Previously Presented) The hydrogel contact lens of claim 228 wherein said core polymeric material comprises a siloxane-containing macromer or a siloxane containing monomer as said oxyperm material and N-vinyl pyrrolidone as said ionoperm material.

Claim 230 (Previously Presented) .The hydrogel contact lens of claim 229 wherein said surfaces are modified by a plasma treating process.

Claim 231 (Previously Presented) The hydrogel contact lens of claim 230 wherein said lens can be worn for about 7 days with less than about 8% corneal swelling.

Claim 232 (Previously Presented) The hydrogel contact lens of claim 230 wherein said lens is worn for about 7 days with less than about 4% corneal swelling.

Claim 233 (Previously Presented) The hydrogel contact lens of claim 230 wherein said lens can be continuously worn for about 30 days.

Claim 234 (Previously Presented) The hydrogel contact lens of claim 230 wherein said lens has an oxygen permeability of at least 75 barrers .

Claim 235 (Currently Amended) A method of using a contact lens as an extended wear lens, said lens having ophthalmically compatible modified surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids, said lens comprising a polymeric material which has a high oxygen permeability and a high ion or water permeability, and which has at least one continous pathway between said modified surfaces for oxygen surfaces, said polymeric material being formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material, and

(b) an ionoperm polymerizable material,

wherein said modified surfaces are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes;

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids;

wherein said lens allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids without having substantial amounts of lipid absorption; and

wherein said ophthalmic lens has an oxygen permeability of at least about 70 barrers and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.4 x 10^{-6} [10-6] cm^2 [cm2] /sec or (2) an Ionoflux Diffusion Coefficient of greater than about 6.4 x 10^{-6} [10-6] mm^2 [mm2]/min, wherein said ion permeability is measured with respect to sodium ions;

said method comprising the steps of:

(a) applying said lens to the ocular environment, and

(b) allowing said lens to remain in continuous ~~continous~~ intimate contact with the ocular environment for a period of at least 24 hours.

Claim 236 (Previously Presented) The method of claim 235 wherein said lens has an oxygen permeability of at least about 77 barrers.

Claim 237 (Previously Presented) The method of claim 235 wherein said intimate contact period is at least 4 days.

Claim 238 (Previously Presented) The method of claim 235 wherein said intimate contact period is about 7 days.

Claim 239 (Previously Presented) The method of claim 235 wherein said intimate contact period is about 14 days.

Claim 240 (Previously Presented) The method of claim 235 wherein said intimate contact period is about 30 days.

Claim 241 (Previously Presented) The method of claim 235, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 8% corneal swelling.

Claim 242 (Previously Presented) The method of claim 235, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less that about 6% corneal swelling.

Claim 243 (Currently Amended) An extended wear contact lens comprising a core polymeric material and inner and lower ~~lewer~~ surfaces that are more hydrophilic than said core polymeric material, said core polymeric material formed from a silicone copolymer which provides a high ion permeability and a high oxygen permeability; said silicone copolymer comprising an oxyperm polymerizable material, and an ionoperm polymerizable material; said core polymeric material having an oxygen permeability equal to or greater than 69 barrers; wherein said extended wear contact lens can be continuously worn for at least fourteen days on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

244 (Currently Amended) A siloxane hydrogel contact lens comprising a core polymeric material having hydrophilically modified surfaces that are more hydrophilic that said core material, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids, said core polymeric material being formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material, and

(b) an ionoperm polymerizable material,

wherein said lens has an oxygen permeability of at least about 69 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater than about 6.4 x 10^{-6} ~~10-6~~ mm^2/sec or an Ionoton Ion Permeability Coefficient of greater than about 0.4 x

10^{-6} ~~10-6~~ cm^2/min to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids,

wherein said hydrogel contact lens is adapted for at least 14 days of continuous wear on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

Claim 245 (Currently Amended) A biocompatible contact lens having an oxygen permeability of at least about 69 barrers and an ion permeability characterized by an Ionoton Ion Permeability Coefficient of greater than about 0.4 x 10^{-6} ~~10-6~~ cm^2/min, said lens comprising:

(a) a polymeric core material in the shape of contact lens having an inner and outer surface; and

(b) said surfaces of said core material being surface treated ~~(modified)~~ to form surfaces that are more hydrophilic than said core material;

said lens having adequate movement on the eye without blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial lipid adsorption, and without causing substantial wearer discomfort for a period of continuous ~~continous~~ contact for 14 days.

Claim 246 (Currently Amended) A biocompatible sterilizable contact lens having an oxygen permeability of at least about 69 barrers and an ion permeability characterized by an Ionoton Ion Permeability Coefficient of greater than about 0.4 x 10^{-6} ~~10-6~~ cm^2/min, said lens comprising:

(a) a polymeric core material in the shape of contact lens having an inner and outer surface; and

(b) said surfaces of said core material being surface modified to form surfaces that are more hydrophilic than said core material;

said lens having adequate movement on the eye without blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial lipid adsorption, and without causing substantial wearer discomfort for a period of continuous ~~continous~~ contact for 30 days.

Claim 247 (New) A contact lens comprising a polymeric material formed from at least:

(a) an ionoperm polymerizable material comprising at least one of 2-hydroxyethyl methacrylate or N,N-dimethylacrylamide; and

(b) an oxyperm polymerizable material;

wherein said lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton ion permeability coefficient of greater than about 0.25×10^{-3} cm^2/sec, or (2) an Ionoflux diffusion coefficient of greater than about 1.3×10^{-3} mm^2/min, wherein said ion permeability is measured with respect to sodium ions;

wherein said lens is suitable for continuous, intimate contact with ocular tissue and ocular fluids while having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear of at least 24 hours.

Claim 248 (New) The contact lens of claim 247 wherein said ionoperm polymerizable material comprises both 2-hydroxyethyl methacrylate and N,N-dimethylacrylamide.

Claim 249 (New) The contact lens of claim 248 wherein said oxyperm polymerizable material comprises at least one of a siloxane containing macromer or a siloxane containing monomer.

Claim 250 (New) The contact lens of claim 249 wherein said polymeric material is further formed from ethylene glycol dimethacrylate.

Claim 251 (New) The contact lens of claim 250 wherein said lens is autoclaved without lowering either said oxygen transmissibility or said ion permeability below levels sufficient to maintain good corneal health and on-eye movement.

Claim 252 (New) The contact lens of claim 250 wherein said period of wear is at least 4 days.

Claim 253 (New) The contact lens of claim 250 wherein said period of wear is at least 7 days.

Claim 254 (New) The contact lens of claim 247 further comprising polyvinylpyrrolidone at a surface of said lens.

Claim 255 (New) The contact lens of claim 254 wherein said polyvinylpyrrolidone coats said surface of said lens.

Claim 256 (New) The contact lens of claim 247 wherein said period of wear is at least 4 days.

Claim 257 (New) The contact lens of claim 247 wherein said period of wear is at least 7 days.

Claim 258 (New) The contact lens of claim 247 wherein said lens has an equilibrium water content of about 10 to about 30 weight percent.

SUPPORT FOR THE NEW CLAIMS

Claims 247 to 258 are new. Support for the new claims can be found throughout the detailed specification and original claims. For example, detailed support for claim 247 can be found on page 10, beginning at line 23, where applicants describe ionoperm polymerizable materials to include 2-hydroxyethyl methacrylate or N,N-dimethylacrylamide; under Tables E on pages 91, applicants describe preferred Ionoton values of greater than about 0.25×10^{-3} cm^2/sec in Table F on pager 96 and in Example F 5 applicants further describe Ionoflux values including those greater than about 1.3×10^{-5} mm^2/min. Additional support for claim 249 can be found under the section labeled oxyperm polymerizable materials on page 9 of specification; support for claim 250 can be found on page 11, line 11; support for claims 254 and 255 can be found in Examples F 1 to F 12 and Table F on pages 91-96; support for claims 251 to 253 and 256 to 258 should be readily apparent from the disclosure. Accordingly, it is respectfully submitted that the addition of new claims 247 to 258 does not raise any new matter issues.

REMARKS:

In the Office Action mailed on November 6, 2004, the Examiner allowed claims 183-242 and rejected claims 243-246 under 35 U.S.C. § 102(b) over Nicolson et al U.S. Patent No. 5,649,811. ("Nicolson '811 Patent"). The courtesy of the Examiner in allowing claims 183-242, believed to be claims 159-242, is appreciated.

For avoidance of doubt, the examiner is requested to indicate that pending claims 159 to 182 are also in condition for allowance, as reflected in the examiner's Notice of Allowability of December 2, 2002. Applicants believe that the omission of claims 159 to 182 as allowable was inadvertent, and have interpreted the Office Action as allowing these claims.

Applicant respectfully requests reconsideration of the pending claims in view of the above amendments to the claims and the following remarks.

In particular Applicants have made minor amendments to the claims marked "currently amended", as reflected above, to clarify the fact that superscripts are present in appropriate claims, and correct typographical errors.

THE REJECTION OF CLAIMS 243-246 IS OVERCOME AS THE NICOLSON '811 PATENT IS NOT PRIOR ART UNDER 35 U.S.C. § 102(b)

The Nicolson '811 Patent, SN 08/682,452, does not qualify as prior art. The Nicolson '811 Patent is a parent application of the present application as indicated in the filing receipt. Clearly, priority of SN 08/682,452 was claimed upon the August 17, 2000 filing date of the present application and such priority was granted by the filing receipt where the SN 08/682,452

application, now the Nicolson '811 Patent, is specifically identified. Accordingly, withdrawal of the rejection under claims 243-246 under 35 U.S.C. § 102(b) is requested.

New claims 247 to 258 claim a species of the invention. In particular, independent claim 247 claims a lens having a specific ionoperm polymerizable material, with the lens having a extended period of wear of 24 hours without substantial lipid adsorption. Dependant claims 248 to 258 depend on independent claim 247.

A notice of allowance is solicited.

For avoidance of doubt, applicants' additionally petition for an extension of time under 37 C.F.R. §1.136, which is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account Number 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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